

SECTION 5. 510(k) SUMMARY

DEC 11 2012

Angled XiVE® MP and ANKYLOS® Balance Base Abutments1. Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Contact Person: Helen Lewis
Telephone Number: 717-849-4229
Fax Number: 717-849-4343

Date Prepared: November 2, 2012

2. Device Name:

- Proprietary Name: Angled XiVE® MP and ANKYLOS® Balance Base Abutments
- Classification Name: Endosseous dental implant abutment
- CFR Number: 872.3630
- Device Class: II
- Product Code: NHA

3. Predicate Device:

- Angled Multi-Unit Abutments cleared in K050406 (NOBELSPEEDY™ Implants)
- Straight ANKYLOS® Balance Base Abutments cleared in K073075 (FRIADENT Implant Systems)
- Straight FRIADENT® MP Abutments cleared in K994174 (FRIALIT-2® MH-2 ABUTMENT)

4. Description of Device:

The Angled XiVE® MP and ANKYLOS® Balance Base Abutment are endosseous dental implant abutments which provide a platform for prosthetic restoration with bridges or bar constructions in conjunction with XiVE® and ANKYLOS® implants. The abutments are provided with an angulation of 15° and 30° at gingival heights ranging from 2.0mm – 5.0 mm for angled XiVE® MP abutments and from 3.0mm – 4.5mm for angled ANKYLOS® Balance Base abutments, respectively. The angled ANKYLOS® BalanceBase Abutments are offered in 3.45mm diameter (compatible with all ANKYLOS® implants). The angled XiVE® MP Abutments are offered in diameters ranging from 3.4mm (compatible with 3.4mm diameter XiVE® implants) to 3.8mm (compatible with XiVE® implants of 3.8mm – 5.5mm diameter). The abutments are connected to the corresponding implants by a central screw which mates with the internal thread of the implant. The abutments and the abutment screws are machined from Titanium Alloy (Ti6AL4V ELI) conforming to ASTM F136 (*Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial Alloy for Surgical Implant Applications)*).

The Angled XiVE® MP and ANKYLOS® Balance Base Abutments facilitate the SmartFix™ treatment concept in which the angled abutments are used in combination with straight abutments on a of minimum four (4) implants (with two posterior implants placed at an angle of up to 45° in the posterior region) to support prosthetic restorations.

In addition to the introduction of the Angled XiVE® MP and ANKYLOS® Balance Base Abutments, a modification to the indications for use statements of the currently marketed straight FRIADENT® MP and straight ANKYLOS® Balance Base Abutments is implemented as part of this premarket notification.

5. Indications for Use:

The angled XiVE® MP and angled ANKYLOS® Balance Base Abutments are indicated for use in prosthetic restorations with XiVE® and ANKYLOS® implants, respectively, and bridges or bar overdentures using a minimum of 2 implants. In edentulous jaws, immediate loading is possible using a minimum of 4 implants. Implants may be tilted up to 45°. When used with angulations between 30° and 45° in edentulous arch, a minimum of four implants must be used and splinted.

The straight FRIADENT® MP and straight ANKYLOS® Balance Base Abutments are indicated for use in prosthetic restorations with XiVE®, FRIALIT® and ANKYLOS® implants, respectively, and bridges or bar overdentures using a minimum of 2 implants. In edentulous jaws, immediate loading is possible using a minimum of 4 implants.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics.

The material used for the Angled XiVE® MP and ANKYLOS® Balance Base Abutments, Ti6Al4V, is the same Titanium Alloy material as is used in the legally marketed predicate device. The proposed devices are similar in terms of design, angulations, sizes, indications for use and incorporate the same technological characteristics as the predicate devices.

In order to assure safety of the Angled XiVE® MP and ANKYLOS® Balance Base Abutment, a failure mode, effect and criticality analysis has been performed. There were no unacceptable risks regarding the function of the Angled XiVE® MP and ANKYLOS® Balance Base Abutments.

Non-Clinical Performance Data.

Representative fatigue data from testing is included and the results support substantial equivalence.

Conclusion as to Substantial Equivalence:

Based on the comparison of the indications for use, the technological characteristics and the nonclinical testing it can be concluded that the Angled XiVE® MP and ANKYLOS® Balance Base Abutment are substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

December 11, 2012

Ms. Helen Lewis
Director, Corporate Regulatory Affairs
DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street, Suite 60W
YORK PA 17404

Re: K122268

Trade/Device Name: Angled XiVE[®] MP and ANKYLOS[®] Balance Base Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: November 2, 2012
Received: November 13, 2012

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K1 22268

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K122268

Device Name: Angled XiVE[®] MP and ANKYLOS[®] Balance Base Abutments

Indications for Use:

The angled XiVE[®] MP and angled ANKYLOS[®] Balance Base Abutments are indicated for use in prosthetic restorations with XiVE[®] and ANKYLOS[®] implants, respectively, and bridges or bar overdentures using a minimum of 2 implants. In edentulous jaws, immediate loading is possible using a minimum of 4 implants. Implants may be tilted up to 45°. When used with angulations between 30° and 45° in edentulous arch, a minimum of four implants must be used and splinted.

The straight FRIADENT[®] MP and straight ANKYLOS[®] Balance Base Abutments are indicated for use in prosthetic restorations with XiVE[®], FRIALIT[®] and ANKYLOS[®] implants, respectively, and bridges or bar overdentures using a minimum of 2 implants. In edentulous jaws, immediate loading is possible using a minimum of 4 implants.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2012.12.05
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: _____